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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/930,494	08/16/2001	Reid W. Von Borstel	1331-352	1560

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EXAMINER	
YOUNG, JOSEPHINE 13	
ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 03/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/930,494	Applicant(s) VON BORSTEL ET AL.	
	Examiner Josephine Young	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-50 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-50 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-15, 18-41 and 47-49, drawn to methods for treating or preventing pathophysiological consequences of mitochondrial respiratory chain dysfunction using a pyrimidine nucleoside or acyl derivative of a pyrimidine nucleoside, classified in class 514, subclass 49.

II. Claims 1-11, 17-41 and 47-48, drawn to methods for treating or preventing pathophysiological consequences of mitochondrial respiratory chain dysfunction using a phosphocholine derivative of a pyrimidine nucleotide, classified in class 514, subclass 51.

III. Claims 1-11, 16, 18-41 and 47-48, drawn to methods for treating or preventing pathophysiological consequences of mitochondrial respiratory chain dysfunction using a nucleobase, such as orotic acid, or an alcohol ester of a nucleobase, classified in class 514, subclass 256^{+}.

IV. Claims 1-11, 18-41 and 47-48, drawn to methods for treating or preventing pathophysiological consequences of mitochondrial respiratory chain dysfunction using a pyrimidine nucleotide precursor, other than a pyrimidine nucleoside, an acyl derivative of a pyrimidine nucleoside, a phosphocholine derivative of a pyrimidine nucleotide, a nucleobase and an alcohol ester of a nucleobase, classified in class 514, subclass 49^{+}, 256^{+}.

V. Claims 42-43, drawn to methods for reducing side effects of cytotoxic cancer chemotherapy agents using a pyrimidine nucleoside or acyl derivative of a pyrimidine nucleoside, classified in class 514, subclass 49.

VI. Claims 42-43, drawn to methods for reducing side effects of cytotoxic cancer chemotherapy agents using a phosphocholine derivative of a pyrimidine nucleotide, classified in class 514, subclass 51.

VII. Claims 42-43, drawn to methods for reducing side effects of cytotoxic cancer chemotherapy agents using a nucleobase, such as orotic acid, or an alcohol ester of a nucleobase, classified in class 514, subclass 256^{+}.

VIII. Claims 42-43, drawn to methods for reducing side effects of cytotoxic cancer chemotherapy agents using a pyrimidine nucleotide precursor, other than a pyrimidine nucleoside, an acyl derivative of a pyrimidine nucleoside, a phosphocholine derivative of a pyrimidine nucleotide, a nucleobase and an alcohol ester of a nucleobase, classified in class 514, subclass 49^{+}, 256^{+}.

IX. Claim 44, drawn to methods for diagnosing mitochondrial disease using a pyrimidine nucleoside or acyl derivative of a pyrimidine nucleoside, classified in class 514, subclass 49.

X. Claim 44, drawn to methods for diagnosing mitochondrial disease using a phosphocholine derivative of a pyrimidine nucleotide, classified in class 514, subclass 51.

XI. Claim 44, drawn to methods for diagnosing mitochondrial disease using a nucleobase, such as orotic acid, or an alcohol ester of a nucleobase, classified in class 514, subclass 256^{+}.

XII. Claim 44, drawn to methods for diagnosing mitochondrial disease using a pyrimidine nucleotide precursor, other than a pyrimidine nucleoside, an acyl derivative of a pyrimidine nucleoside, a phosphocholine derivative of a pyrimidine nucleotide, a nucleobase and an alcohol ester of a nucleobase, classified in class 514, subclass 49^{+}, 256^{+}.

XIII. Claims 46 and 50, drawn to pyruvyl derivatives of uridine and pharmaceutical compositions comprising a pyrimidine nucleoside or acyl derivative of a pyrimidine nucleoside with pyruvic acid or creatine, classified in class 514, subclass 49.

XIV. Claims 46 and 50, drawn to pharmaceutical compositions comprising a phosphocholine derivative of a pyrimidine nucleotide with pyruvic acid or creatine, classified in class 514, subclass 51.

XV. Claims 46 and 50, drawn to pharmaceutical compositions comprising a nucleobase, such as orotic acid, or an alcohol ester of a nucleobase with pyruvic acid or creatine, classified in class 514, subclass 256^{+}.

XVI. Claims 46 and 50, drawn to pharmaceutical compositions comprising a pyrimidine nucleotide precursor, other than a pyrimidine nucleoside, an acyl derivative of a pyrimidine nucleoside, a phosphocholine derivative of a

pyrimidine nucleotide, a nucleobase and an alcohol ester of a nucleobases, with pyruvic acid or creatine, classified in class 514, subclass 49^{+}, 256^{+}.

Claims 1-11, 18-41 and 47-48 link Groups I-IV and will be examined together with the Group that is elected as it pertains to the elected invention. Claims 42-43 link Groups V-VIII and will be examined together with the Group that is elected as it pertains to the elected invention. Claim 44 links Groups IX-XII and will be examined with the Group that is elected as it pertains to the elected invention. Claims 46 and 50 link Groups XIII-XVI and will be examined together with the Group that is elected as it pertains to the elected invention.

The inventions are distinct, each from the other because of the following reasons:

Groups I-IV are unrelated. Similarly, Groups V-VIII are unrelated. Groups IX-XII are unrelated. Groups XIII-XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to methods and compositions using patentably distinct compounds with different functions. The compounds used/contained in Groups I, V, IX and XIII are nucleosides and their acyl derivatives. The compounds used/contained in Groups II, VI, X and XIV are phosphocholine derivatives of nucleotides. The compounds used/contained in Groups III, VII, XI and XV are nucleobases without a carbohydrate moiety. The compounds used/contained in Groups IV, VIII, XII and XVI are compounds that do not contain the functionality described in

the other divergent groups. Therefore, the compound used/contained of one method/composition do not render obvious the method/composition of another.

Groups I-IV are unrelated to Groups V-VIII and Groups IX-XII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to patentably distinct methods with different effects. The effect of the methods of Groups I-IV is to treat or prevent a pathophysiological consequence, i.e. a disease. The effect of the methods of Groups V-VIII is to reduce the side effect of a drug. The effect of the methods of Groups IX-XII is to diagnose a disease. Therefore, the methods of one do not render obvious the methods of another.

Groups XIII-XVI are related to Groups I-IV, Groups V-VIII and Groups IX-XII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products and compositions of Groups XIII-XVI, for example the pyruvyl derivatives of uridine, can be used in materially different processes, namely the process of Groups I-IV, the process of Groups V-VIII or the process of Groups IX-XII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter, restriction for examination purposes as indicated is proper. A reference for one group could not reasonably be expected to be a reference for another. Further, searching all of

the inventions constitutes a burdensome search, as a thorough search comprises a search of foreign patents and non-patent literature, as well as the appropriate U.S. patent classifications. To search the sixteen independent and distinct inventions, set forth supra, would indeed impose an undue burden upon the examiner in charge of this application.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even if the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Josephine Young whose telephone number is (703) 605-1201. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached at (703) 308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

JY
March 17, 2003

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600